



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,496	08/01/2001	John P. Hall	P-5211	7112

26253 7590 12/31/2003

BECTON, DICKINSON AND COMPANY
1 BECTON DRIVE
FRANKLIN LAKES, NJ 07417-1880

EXAMINER

QUAN, ELIZABETH S

ART UNIT	PAPER NUMBER
----------	--------------

1743

DATE MAILED: 12/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/920,496

Applicant(s)

HALL ET AL.

Examiner

Elizabeth Quan

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-25 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the clamp must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claim 22 is objected to because of the following informalities: The fact that the multi-well plate has a plurality of wells has been recited twice. Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 10, 16, 20-22, 24, and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification, drawings, and original claims do not provide support for the clamp in its specific configuration, the central portion of the gasket in contact with the upper surface of the multi-well plate and the sides of the gasket not in contact with the upper surface

Art Unit: 1743

when the upper section is at rest, sides of the upper section urged toward the upper surface when the sidewalls are flexed, and both the upper section and sidewalls of the lid made of resiliently flexible material in which the instant specification only states the types of materials used and the original claims only recite a flexible curvilinear section. In fact, the immediate specification discloses that the lid is made of materials such as steel, stainless steel, and the like.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 10, 16, 22, 23 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,436,351 to Gubernator et al.

Gubernator et al. disclose a cover, which is adapted for mechanical manipulation, for sealing and securing a multi-well plate (16) with an upper surface, plurality of wells having openings disposed in the upper surface, and skirt disposed on an edge of the plate (see ABSTRACT; FIGS. 1A, 1B, and 2; COL. 1, lines 65-67; COL. 2, lines 1 and 2). The cover comprises a lid (26) along with its curvilinear upper section that is dimensionally suited to covering or sized to overlie a multi-well plate (16) (see FIGS. 1A, 1B, and 2). Since both the immediate application and Gubernator et al. fabricate their lids from metal, it appears the lid along with its upper section and sidewalls would have a flexible curvilinear section since the lid is disclosed as being formed from a metal, such as anodized aluminum. The term flexible is a

Art Unit: 1743

relative term, and all materials have a certain degree of flexibility, such that the lid of Gubernator et al. would have a certain degree of flexibility in its curvilinear section. The lid (26) has a plurality of projections (28) and apertures (27,40,43) (see FIGS. 1A, 1B, and 2). The projections, which are positioned on the sidewall at an end opposite to the end of the sidewall that depends from the upper section of the lid, may be considered a clamp that engages an edge of the multi-well plate. When the reaction system is not assembled or the lid is not pressed against the gasket and multi-well plate (16), the gasket (24), which is directly below the lid (26), is uncompressed (see FIGS. 1A, 1B, and 2). The gasket (156) may be made of thermoplastic polymers or elastomers, such as silicone rubber (see COL. 4, lines 60-62). The material having a durometer of Shore 15A or less and having a high degree of chemical resistance to dimethyl sulfoxide is inherent to the materials used to make the gasket since the gasket (156) is made from thermoplastic polymers or elastomers, as disclosed in the specification. The lid (26) has at least two sidewalls integrally depend at an end thereof from the sides of the upper section of the lid and extend substantially perpendicular to the curvilinear section of the lid (26) for grasping engagement with the multi-well plate to secure the lid sealingly to the multi-well plate (see FIGS. 1A, 1B, and 2). The side walls have an attachment means in the form of projections or arms with a catch portion, which directly performs the function of attaching onto the notches (21) of the multi-well plate (16) (see FIGS. 1A, 1B, 2, 3A, and 3B). When the lid is positioned above the surface of the multi-well plate and downward force is applied to the lid to cover against the multi-well plate, the curvilinear upper section resiliently deforms to cause the sidewalls to resiliently flex about the multi-well plate (see COL. 4, lines 60-67; COL. 5, lines 1-12). With continued application of downward force the sidewalls resiliently grasp the multi-well

Art Unit: 1743

plate to secure the lid the multi-well plate with the upper section in closely overlying relation to the multi-well plate surface (see COL. 4, lines 60-67; COL. 5, lines 1-12). When the lid is secured to the multi-well plate, the gasket is fixed or made stationary to the underside of the lid, dimensioned to compressingly abut the surface of the multi-well plate, and seals the wells against ingress and egress of fluids and materials (figs. 3a and 3b; col. 4, lines 63-65). The occurrence of deformation and flexing with the application of a downward force is inherent to the structure. It is noted that method limitations in device claims have no patentable weight in device claims if the prior art apparatus teaches all the structural limitations of the claim (MPEP 2114).

3. Claims 10-15, 17, 18, 20-25 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,486,401 to Warhurst et al.

Warhurst et al. disclose an assembly of a multi-well plate (10) and a cover (20) for the multi-well plate (see figs. 3a and 3b).

The plate comprises an upper surface, plurality of wells (12) having openings disposed in the upper surface, and a skirt disposed on an edge of the plate (fig. 3a).

The cover comprises a lid (22) with an upper section that is sized to overlie the multi-well plate (figs. 3a and 3b). The lid is made of plastic or metal, which are resiliently flexible materials (col. 3, lines 25-27; col. 4, lines 6-8). Furthermore, the instant specification discloses that the lid is made from metal. Since both the immediate application and Warhurst et al. fabricate their lids from metal, it appears the lid is resiliently flexible. The use of legs, which may be crimped in place or spring loaded, for clamping the lid to the multi-well plate is evidence that the lid is resiliently flexible (col. 3, lines 27 and 28). Fig. 16 shows the cover with the

Art Unit: 1743

clamping legs in the open position, revealing a curvilinear bend in the cover. Fig. 17 shows the cover with clamping legs in the closed position in which the cover is now flat. This is evidence that the lid is resiliently flexible. The lid has a plurality of sidewalls integrally depending from the sides of the upper section of the lid and extending substantially perpendicular to the upper section for grasping engagement with the multi-well plate to sealingly secure the lid to the multi-well plate (figs. 1-10, 14, 16, 17). When the lid is positioned above the surface of the multi-well plate and downward force is applied to the lid to press the cover against the multi-well plate, the curvilinear section resiliently deforms to cause the sidewalls to resiliently flex about the multi-well plate (figs. 1-10, 14, 16, 17). Specifically, when the upper section is in the resting position with the legs open, such that the central portion of the upper section are concave with the central portion of the gasket between the sidewalls of lid contacting the upper surface of the multi-well plate, portions of the gasket affixed to the underside of the upper section of the lid are not in contact with the upper surface of the multi-well plate. With continued application of downward force, the sidewalls resiliently flex and grasp the multi-well plate to secure the lid to the multi-well plate with the upper section in closely overlying relation to the multi-well plate surface, such that the gasket is compressed between the underside of the lid and upper surface of the multi-well plate to seal the wells (figs. 1-10, 14, 16, 17). A non-stick sealing layer (26) is bonded, made integral, or attached to the compressible layer (24), which in turn is bonded, made integral, or attached to lid (22) (col. 3, lines 62-66). The sealing layer is made of polypropylene, Teflon, Mylar, or similar material (col. 4, lines 1 and 2). The compressible layer is made of a soft material, such as neoprene rubber, silicone rubber, silicone foam, or polyurethane foam that helps supply an even force to the sealing layer covering the wells of the multi-well plate (col. 4,

Art Unit: 1743

lines 1-5). The sealing layer and compressible layer compressingly abuts the surface of the multi-well plate and seals the wells against ingress and egress of fluids and materials when the lid is sealingly secured to the multi-well plate. The material having a durometer of Shore 15A or less and having a high degree of chemical resistance to dimethyl sulfoxide is inherent to the materials used to make the gasket since the gasket (156) is made from thermoplastic polymers or elastomers, as disclosed in the specification. The sidewalls include notched tabs with locator holes (29) for facilitating the gripping of the cover by mechanical means (figs. 1-10). The sidewalls further include stacking lugs projecting downward from the sidewalls (figs. 1-10). The sidewalls further include means for aligning the cover with an adjacent cover when the cover is in a stack of like covers (figs. 3a and 4). The means for aligning includes stacking locators positioned in the sidewalls in which the stacking locators engage the stacking lugs of the adjacent cover (figs. 3a and 4).

It is noted that method limitations in device claims have no patentable weight in device claims if the prior art apparatus teaches all the structural limitations of the claim (MPEP 2114).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1743

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Alternatively, claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,486,401 to Warhurst et al.

Warhurst et al. do not explicitly disclose that the gasket material has a durometer of Shore 15A or less and high degree of chemical resistance to dimethyl sulfoxide. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Warhurst et al. to make the gasket from a material having a durometer of Shore 15A or less and high chemical resistance to dimethyl sulfoxide in order to obtain a gasket of desired chemical and physical properties as necessary for performing certain assays, for example, a desired degree of flexibility sufficient to seal the wells of a multi-well plate.

Art Unit: 1743

8. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,486,401 to Warhurst et al. in view of U.S. Patent No. 6,379,626 to Munson et al. and U.S. Patent No. 6,103,199 to Bjornson et al.

Referring to claim 19, Warhurst et al. do not disclose that the lid is made from steel, spring steel, or stainless steel. However, Munson et al. disclose that the cover is made from stainless steel for corrosion resistance (see COL. 2, lines 59-61). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Warhurst et al. to make the cover from stainless steel as in Munson et al. to prevent corrosion.

Warhurst et al. do not address the thickness of the cover. However, Bjornson et al. disclose that cover thicknesses are more usually at least about 500 micrometers or 0.019685039370079 inches, which is within the recited range, as required for different materials with different mechanical properties (see COL. 25, lines 65-67; COL. 26, line 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Warhurst et al. to provide a cover thickness between 0.015" and 0.024" as in Bjornson et al. to obtain a cover exhibiting certain properties to create an effective seal with the multi-well plate. Furthermore, it has been held that discovering optimum ranges is within ordinary skill in the art (*In re Aller*, 105 USPQ 233).

9. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,486,401 to Warhurst et al. in view of U.S. Patent No. 5,741,463 to Sanadi.

Warhurst et al. disclose the cover with legs that may be crimped in place or spring loaded that engages an edge of the multi-well plate. Sanadi discloses that a variety of mechanisms,

Art Unit: 1743

including clips or clamps. In a particular embodiment, Sanadi uses clamps to sealingly secure the lid and gasket onto the plate as an alternative means to clips (see fig. 3). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Warhurst et al. to provide clamps on the sidewall at an end opposite to the end of the sidewall that depends from the upper section of the lid to sealingly secure the lid and gasket onto the plate as an alternative means to clips as taught by Sanadi.

Response to Arguments

10. Applicant's arguments with respect to claims 10-25 have been considered but are moot in view of the new ground(s) of rejection.

11. Applicant's arguments filed 10/16/2003 have been fully considered but they are not persuasive.

12. Applicant states that both Gubernator and Moring disclose covers, which are rigid and flat. Examiner has withdrawn the art rejection based on Moring. However, Gubernator has never mentioned that the cover is rigid. Gubernator might show a flat cover in the drawings, but that does not it is rigid. Gubernator simply states the cover may be made of metal or plastic, and the instant specification mentions that the cover is made of metal, such that it would be reasonable that the prior art and instant inventions would have the same properties. The specification and original claims never mentions lids along with the upper section and the sidewalls being made of "flexible" materials. Warhurst et al. has been cited in an art rejection that shows a lid that is made of flexible materials.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan
Examiner
Art Unit 1743


Jill Warden
Supervisory Patent Examiner
Technology Center 1700